

Appl. No.: 10/771,622
Amdt. dated 06/08/2005
Reply to Office action of March 8, 2005

REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the remarks that follow. Claims 33-81 are pending in the application.

Claims 33-81 stand rejected under 35 U.S.C. §101 as claiming the same invention as claimed in either one of U.S. Patent Nos. 5,614,206 or 6,753,007. Applicants respectfully traverse these rejections.

Applicants respectfully submit that the two statutory double patenting rejections are improper because the pending claims are not directed to identical subject matter as claimed in the two cited patents. Under such circumstances, a statutory double patenting rejection is improper. Applicants direct the Examiner's attention to Section 804 of the MPEP, where it clearly states that for two patents to issue on the "same invention," the claims must be identical in subject matter (i.e., identical in scope). Section 804 of the MPEP goes further to state that a reliable test for statutory double patenting is to query whether an embodiment of the invention falls within the scope of one claim, but not the other. The MPEP states that "if there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist" (Section 804, Part II. A.).

In the present case, identical subject matter is clearly not being claimed in the pending application as compared to the two cited patents. With respect to the '206 patent, it is noted that the claims of the patent are directed to a pellet having a controllable dissolution rate and a method of delivering medicament *in vivo* by implanting such a pellet. In each of the claims, the pellet is prepared by a process comprising mixing a first powder with an optional second powder in water to form a mixture which is thereafter formed into a pellet. In contrast, the claims of the present invention are directed to a composite comprising a first region comprising calcium sulfate and at least one medicament and a second region comprising calcium sulfate and at least one medicament, wherein the dissolution rates of the two regions are different. The concept of multiple regions within a single composite is clearly not set forth in the claims of the '206 patent. There is nothing in any of the claims of the cited patent regarding separate defined regions within the pellet. Thus, a statutory double patenting rejection based on the '206 patent is clearly

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improper. There are multiple embodiments that could be envisioned that would literally infringe the claims of the cited patent but fail to fall within the scope of the pending claims. For instance, a pellet comprising a single homogenous mixture of powders could conceivably fall within the scope of the claims of the '206 patent, but clearly would fall outside the scope of the pending claims, which expressly require two separate regions with different rates of dissolution. For this reason, Applicants respectfully request reconsideration and withdrawal of this rejection with respect to the '206 patent.

With respect to the rejection based on the '007 patent, which issued from a parent application related to the present application, Applicants also respectfully submit that identical subject matter is not being claimed. Again, using the test set forth in the MPEP, one can envision embodiments that would fall within the scope of one or more claims of the cited patent, but not within the scope of the pending claims. Under such circumstances, it cannot be said that the application claims identical subject matter as the cited patent. For instance, each claim of the pending application requires at least two regions comprising calcium sulfate and a medicament, wherein the medicaments are selected from the group consisting of antibiotics, chemotherapeutic agents, growth factors, analgesics, and combinations thereof. Thus, every claim in the pending application requires that the medicaments in each region fall within one of the above-listed categories. This subject matter is not identically claimed in any claim of the '007 patent. No claim of the '007 patent is directed to a composite having a first region and a second region wherein each region comprises a medicament selected from the groups listed above.

Claim 9 of the '007 could be viewed as the closest claim in terms of subject matter, but Claim 9 still fails to read on identical subject matter as presently claimed. Claim 9 is directed to a composite having a first region and a second region, wherein both regions comprise a medicament and wherein the medicament is selected from a list of specific compounds. While some of the compounds listed in Claim 9 of the '007 patent fall within the more general classifications referred to in the claims of the pending application, the scope of Claim 9 is not identical to the scope of any of the pending claims. There are numerous antibiotics, chemotherapeutic agents, growth factors, and analgesics that are not listed in Claim 9, but which would fall within the scope of the pending claims. In other words, numerous embodiments could

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be envisioned that would literally infringe the pending claims, but would not literally infringe Claim 9 of the '007 patent.

Conversely, there are numerous embodiments that could be envisioned that would literally infringe the claims of the '007 patent without literally infringing any of the claims of the pending application. For example, a composite comprising two regions, each region comprising a medicament, wherein the medicament is not an antibiotic, chemotherapeutic agent, growth factor, analgesic, or a combination thereof, would not literally infringe any of the pending claims. However, such a composite could fall within the scope of one or more claims of the '007 patent. In light of the foregoing, Applicants respectfully submit that the statutory double patenting rejection is improper and request reconsideration and withdrawal of the rejection as applied to the '007 patent.

As Section 804 of the MPEP admonishes, the difference between "domination" and double patenting should be carefully considered in order to avoid confusing the two concepts. As explained in the MPEP, one patent or application dominates another patent or application where a claim of the first application or patent fully encompasses or reads on an invention defined in a narrower claim in the second application. Domination alone is insufficient to support a double patenting rejection. Significant overlap in subject matter, even to the point of domination, does not necessitate a double patenting rejection unless a claim in each document can be considered to cover identical subject matter, meaning the two claims have identical scope.

It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

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